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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/764,546	SPITLER ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *56 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *56 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

. The Response filed March 3, 2004 in response to the Office Action of November 28, 2004 is acknowledged and has been entered. Claims 56 and 61 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 102

4. Claim 61 remains rejected under 35 USC 102 (b) for the reasons previously set forth in the paper mailed November 28, 2004, Section 5, pages 2-4.

Applicant argues that the methods disclosed in the Kleinerman publications fail to anticipate the claimed methods because neither publication teaches or suggests the use of MTP-PE to ameliorate the side effects of treatment with a second neoplastic agent.

The argument has been considered but has not been found persuasive because the method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes to the same population, that is subjects that had been treated with an anti-neoplasia agent.

Applicant argues that Examiner's assumption that the population of subjects treated with a second neoplastic agent is the same population with mucositis is faulty. Applicant cites Berger et al in (Cancer:Prinicples and Practice of Oncology (De Vita, Jr. Et al., Eds. 6th Ed, 2001) Exhibit A, page 2881 to disclose that approximately 40% of patients receiving chemotherapy or radiotherapy develop oral mucositis and that risk factors for developing

mucositis are known, thus only a discrete subset of patients that develop or are at risk for mucositis would benefit from the treatment of the claimed methods. Applicant argues that mucositis is not an inherent side effect of treatment with a second neoplastic agent and because mucositis is not inherent in the patients receiving anti-neoplastic agents, neither publication of Kleinerman anticipates the claimed methods.

The argument has been considered but has not been found persuasive because the rejection is not drawn to "every individual" but rather is specifically drawn to that subset of patients who present with mucositis, myelosuppression or peripheral neuropathy (see Office Action, page 3). In point of fact, the submitted Exhibit A clearly supports Examiner's rejection in that it demonstrates that 40% of those patents receiving chemotherapy or radiotherapy develop oral mucositis.

Applicant argues that the holding in *Ex parte Novitiski* is inapposite to the instant methods because mucositis does not inherently result from treatment by a neoplastic agent.

The argument has been considered but has not been found persuasive, Applicant has proven conclusively that a subset of approximately 40% of patients receiving chemotherapy or radiotherapy develop oral mucositis and for the reasons of record, the claimed method is anticipated.

Applicant argues that the anti-mucositis effects are observed at dosage levels of MTP-PE that are insufficient to treat neoplastic disease and Applicants provided objective evidence of the anti-mucositis effects of MTP-PE.

The argument has been considered but has not been found persuasive since Applicant is arguing limitations not recited in the claims as currently

constituted. Further, although the references do not specifically teach that the method ameliorates side effects of antineoplasia treatment, the claimed method appears to be the same as the prior art method, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from that taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Applicant reiterates arguments drawn to the failure of the Kleinerman publications to anticipate the claimed methods because neither publication teaches or suggests the use of MTP-PE to ameliorate the side effects of treatment with a second neoplastic agent.

The argument has been considered but has not been found persuasive for the reasons set forth above.

Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. Claim 56 is rejected under 35 USC 102(b) as being anticipated by Kleinerman et al (J. Clin. Oncol., 1991, 9:259-267).

The claim is drawn to a method to ameliorate a side effect, mucositis, of antineoplasia treatment in a subject, which subject is undergoing treatment with an anti-neoplasia agent which comprises administering to

said subject a pharmaceutical composition comprising MTP-PE encapsulated in multilamellar liposomes in combination with said anti-neoplasia agent.

Kleinerman et al, teach a method of treating cancer patients comprising administering L-MTP-PE and one of ADR, CPD, MTX or CTX in combination with L-MTP-PE. The reference specifically teaches that "we believe it is important to combine L-MTP-PE with chemotherapy early in the treatment course rather than waiting until all chemotherapy cycles are completed."

The method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering pharmaceutical compositions of L-MTP-PE in combination with one of four different neoplasia agents to the same population, that is subjects undergoing treatment with an anti-neoplasia agent, thus the claimed method is anticipated because the method will inherently lead to the amelioration of mucositis in the subset of those patients that develop mucositis. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Further, although the reference does not specifically teach that the method ameliorates side effects of antineoplasia treatment, the claimed method appears to be the same as the prior art method, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from that taught by the prior art and to establish patentable

differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

The arguments drawn to the rejection of claim 56 are relevant to the instant rejection.

Applicant argues that neither of the Kleinerman publications teaches or suggests the administration of MTP-PE to a patient that is undergoing treatment with an anti-neoplastic agent. The teaching of the administration of MTP-PE alone teaches away from co-administration therefore, neither publication anticipates the method of claim 56.

The argument has been considered and has been found persuasive. However, given the newly imposed rejection, the argument is now moot and Kleinerman et al, 1991 specifically addresses and teaches the co-administration of MTP-PE and antineoplastic agents.

The arguments drawn to the previous rejection of claims 56 and 61 are relevant to the instant rejection.

Applicant has argued as set forth above. The arguments have been considered but have not been found persuasive for the reasons set forth above.

6. All other objections and rejections imposed in the paper mailed November 28, 2003 are hereby withdrawn.

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 308-3995. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Susan Ungar
Primary Patent Examiner
May 4, 2004